K052482/S1 1/2

OCT 17 2005

Attachment 5

510(k) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes Artimplant AB's summary for the ARTELON Surgical Suture.

SUBMITTER'S NAME	Artimplant AB
ADDRESS:	Hulda Mellgrens gata 5, SE-421 32 Västra Frölunda, Sweden
CONTACT PERSON	Ajrulla Zuta
TELEPHONE NUMBER	+46 31 7465600
FAX NUMBER:	+46 31 7465660
DATE OF SUBMISSION	XXXXXXXX

1. **Identification of device**

   Proprietary Name: Artelon® Surgical Suture
   Common Name: Nonabsorbable Nylon Surgical Suture
   Classification Status: Class II per Regulation §878.5020
   Product Code: GAR-surgical, Nonabsorbable, Synthetic, Polyamide.

2. **Equivalent device**

   ARTELON Surgical Suture, K032160, 11/17/2003.

3. **Description of the Device**

   The device description of the ARTELON Surgical Suture is as follows:

   ARTELON Surgical Sutures are nonabsorbable sterile surgical sutures (i.e. braided threads) prepared from ARTELON (polycaprolactone based poly (urethane urea)) in a multifilament form intended for soft tissue approximation. Due to limited stiffness of the sutures, they appear stretchy during handling. Although ARTELON sutures are nonabsorbable, they degrade slowly over time; the degradation occurs over a prolonged period of time with a gradual reduction of tensile strength of approximately 20% per year. ARTELON Surgical Sutures are uncoated and undyed. The sutures are supplied sterile.
   The product meets all requirements established by the United States Pharmacopoeia (U.S.P) for nonabsorbable surgical sutures.

4. **Intended Use**

   The ARTELON Surgical Suture intended use is for use in soft tissue approximation and/or ligation during surgery. This is the **same intended use** as previously cleared for the ARTELON Surgical Suture, K032160.

5. Discussion of Performance Testing

A collection of tests have been performed in accordance with:

- ISO 10993 standards
- ISO 14971
- USP 26
- Class II Special Control Guidance, Surgical Suture; Guidance for Industry and FDA, June 3, 2003.

6. Conclusion

In summary, the ARTELON Surgical Suture described in the submission is, in our opinion, substantially equivalent to the predicate device. The ARTELON Surgical Suture is substantially equivalent to the device already on the market, and presents no new concerns about safety and effectiveness. Additionally, the devices have identical indication to the predicate device, and the labeling is consistent both with FDA guidance as well as current medical practice.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2005

Artimplant AB
c/o Marie Marlow
CEO
M Squared Associates, Inc.
719 A Street, NE
Washington, DC 20002

Re: K052482
Trade/Device Name: Artelon® Surgical Suture
Regulation Number: 21 CFR 878.5020
Regulation Name: Nonabsorbable polyamide surgical suture
Regulatory Class: II
Product Code: GAR
Dated: September 21, 2005
Received: September 23, 2005

Dear Ms. Marlow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052482

Device Name: Artelon® Surgical Suture

Indications for Use:

Artelon® Surgical Suture is intended for use in general soft tissue approximation and/or ligation during surgery.

Prescription Use ___XX____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052482

(Posted November 13, 2003)